REMARKS

Claims 1-11 are pending in the present application. Two Rule 132 Declarations of Dr. Arko Gorter, author of Gorter et al., Clin. Exp. Immunol. 1992. 87:111-116 and a coauthor of the publication, Durrbach et al., Cancer Gene Therapy, 1999. 6:564-571 are attached hereto. Additionally, a Rule 132 Declaration of Dr. Gerd Ritter, co-inventor of published U.S. Patent Appl. No. 2003/0040027 and author of Ritter et al., Cancer Research. 61:6851-6859, is attached hereto. No new matter is introduced.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oosterwijk et al. (WO 88/08854) as evidenced by the specification in view of Oosterwijk et al. (Seminars in Oncology. 1995. 22(1): 34-41) in view of Robinson et al. (U.S. 5,618,980) and in view of Queen et al. (U.S. 5,530,101). Additionally, claims 1-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Weijtens et al. (The Journal of Immunology, 157:836-843) as evidenced by the specification in view of Oosterwijk in view of Orlandi et al. (Proc. Natl. Acad. Sci. USA, 86:3833-3837) in view of Cabilly et al. (U.S. 4,816,567) in view of Robinson (U.S. 5,618,920), in view of Huston et al. (U.S. 5,258,498) and in view of Queen (U.S. 5,530,101).

As grounds for maintaining these rejections, the Examiner contends that the G250 antibody was also in the possession of Durrbach et al. (Cancer Gene Therapy, 1999. 6:564-571) and Gorter et al. (Clin. Exp. Immunol. 1992. 87:111-116) and Ritter et al.). The Examiner contends that these references "indicate that the G250 antibody was also in the possession" of the authors of each reference, who are not the same as the Rule 132 declarants in this case and that Ritter et al. indicates that the G250 antibody was on sale. Furthermore, the Examiner asserts that such distribution of the G250 antibody to many groups brings into question the restricted use of the antibody under confidentiality agreement.

In response, the Applicants assert that each of the submitted declarations completely address each of the Examiner's alleged deficiencies. For example, in Declaration executed by Dr. Arko Gorter on April 5, 2007, Dr. Gorter attests that, inter alia, "the hybridoma cell was not released to anyone other than the team members who were under [his] control and supervision. . . [and] the hybridoma cell . . . was received from Prof. Sven Warnaar under confidentiality agreements that strictly restricted the use, disclosure and distribution thereof." (amended and emphasis added). In Declaration executed by Dr. Arko Gorter on July 18, 2008, Dr. Gorter attests that, "[he is] a coauthor of a publication Durrbach et al. Cancer Gene Therapy, pp 564-571 (1999) [and] the hybridoma cell was not released to anyone other than the team members who were under [his] control and supervision. . . [and] the hybridoma cell . . . was received from Prof. Sven Warnaar under confidentiality agreements that restricted the use, disclosure and distribution.". The Declarations state that the G250 antibody described in Durrbach et al. and Gorter et al. was provided by the inventors under confidentiality agreement that restricted its use and distribution to third parties. The Applicants respectfully submit, therefore, that the Durrbach et al. and Gorter et al. references do not provide evidence that either the G250 antibody or the G250 hybridoma was publicly available.

Furthermore, in Declaration executed on June 18, 2008, Dr. Ritter attests that, inter alia, "the G250 monoclonal antibody was mentioned in the '027 application as having been "purchased" in Example 1 under paragraph [0013]. However the G250 monoclonal antibody was not "purchased", but was instead "produced" by Sven Warnaar of Centocor, as described on p. 6851 in Ritter et al. [and] in a 1996 agreement, Centocor and the Ludwig Institute for Cancer Research (LICR) agreed that Centocor, through Sven Warnaar, would deliver antibodies, including G250, to LICR. LICR allocated some of the G250 antibodies to [him] to conduct the studies described in the '027 application and in Ritter et al. [and] this allotment of G250 was used only by [him] and members of [his] team who were under [his] control and supervision.". The

Declaration states that the G250 antibody described in Ritter et al. and in U.S. Patent Appl. No. 2003/0040027 were not "purchased", but rather "produced" by Sven Warnaar and allocated to Dr. Ritter's team through a 1996 agreement. The Applicants respectfully submit, therefore, that Ritter et al. and '027 do not provide evidence that either the G250 antibody or the G250 hybridoma was publicly available.

Applicants submit that the G250 antibody was protected by confidentiality and restricted use agreements between Leiden University (Dr. Gorter), Centocor, Dr. Daniel den Hoed Hospital in Rotterdam (Dr. Bolhuis), and Ludwig Institute for Cancer Research (Dr. Ritter). The agreements were transferred from Centocor to Wilex on February 22, 1999. The Declarations submitted in this Response and in previous responses attest to the fact that Dr. Sven Warnaar set bars for the distribution and usage of the G250 antibody prior to allocating the G250 antibody. Clearly, the G250 antibody was not available for public use and was protected by confidentiality and restricted use agreements. There is no evidence of any public deposition or sale of the G250 hybridoma cells. Moreover, applicants submit that many journal articles were published by researchers at the above institutes referring to the G250 antibody by name only, however these researchers were bound by confidentiality agreements to not disclose any proprietary information or distribute the antibody. Thus, the sequence and methods of producing the antibody were never made public.

Applicants respectfully point out that it was not possible to submit declarations executed by Dr. Gorter prior to this response since Durrbach et al. and Gorter et al. had not been cited until the most recent Office Action. With regard to Dr. Ritter's declaration, applicants relied in good faith on the contention that the '027 application is not prior art in the previous response. Accordingly, applicants believe that valid reasons have been tendered for submitting the declarations of Drs. Ritter and Gorter herewith and that the declarations should be considered timely filed.

Applicants, therefore, respectfully request reconsideration and withdrawal of the obviousness rejections under 35 U.S.C. § 103(a).

In view of the foregoing, it is submitted that the present application is now in condition for allowance. Reconsideration and allowance of the Application is requested. The Director is authorized to charge any fees or overpayment to Deposit Account No. 02-2135.

Respectfully submitted,

By _____

Robert B. Murray
Attorney for Applicant
Registration No. 22,980
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
Suite 800, 1425 K Street, N.W.
Washington, D.C. 20005
Telephone: (202) 783-6040
Facsimile: (202) 783-6031

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